

## **REMARKS/ARGUMENTS**

Claims 13-15, 17-20 and 40-47 remain in this application. The subject matter of claim 16 has been incorporated into claims 13 and 40. Claim 16, consequently, has been canceled. No new matter has been added.

The Examiner provisionally rejects claims 13-20 and 40-47 on the grounds of non-statutory obviousness-type double patenting over claims 13-20 of copending application 10/734,337 ("337 Application"). Claims 13 and 40 have been amended to provide that the apparatus includes a powder recovery system that can remove excess powder from the vicinity of the die cavities and recycle recovered powder from the filters back into the die cavities. These features are not included in the claims of the '337 Application. For this reason, Applicants request that the Examiner reconsider and withdraw his obviousness-type double patenting of this application in view of the '337 Application.

The Examiner rejects claims 13, 15, 17, 19, 40, 42 and 46 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,292,017 ("Doepel"). The subject matter of claim 16 has been incorporated into claims 13 and 40 rendering this rejection moot. Applicants request that the Examiner reconsider and withdraw his anticipation rejection in view of Doepel.

The Examiner rejects claims 13, 15-17, 40 and 42-44 under 35 U.S.C. 103 as being unpatentable over Soviet reference 662,370 ("SU '370") taken together with U.S. Patent No. 5,667,158 ("Bullock"). The Examiner asserts that SU '370 discloses an apparatus for compression molding of dosage forms having a suction source, a die cavity having a first port and a second port, wherein the suction assists in the delivery of powder into the die cavity. The Examiner further asserts that SU '370 fails to disclose a powder recovery system to purge powders. The Examiner cites Bullock as showing a reclaim system intended to reuse raw material for pharmaceutical tablets collected from a compression molding machine. Applicants respectfully traverse this rejection.

Claim 13 is directed to an apparatus for forming compressed dosage forms, comprising: a) a suction source; b) a die cavity having (i) a first port for placing said die cavity in flow communication with said suction source, whereby said suction source applies suction to said die cavity, and (ii) a second port for placing said die cavity in flow communication with a supply of powder, whereby said suction source assists said powder in flowing into said die cavity; (c) a filter disposed between said suction source and said second port, whereby suction is applied to said die cavity through said filter; and (d) a punch for compressing said powder in said die cavity so as to form said compressed dosage forms; and (e) a powder recovery system for removing excess powder from the vicinity of said die cavity that also includes a recycling means for recovering powder trapped by said filter and recycling said recovered powder back into said die cavity, either directly or indirectly.

Claim 40 is directed to an apparatus for forming compressed dosage forms, comprising: a) a suction source; b) a die cavity having (i) a first port for placing said die cavity in flow communication with said suction source, whereby said suction source applies suction to said die cavity, and (ii) a second port for placing said die cavity in flow communication with a supply of powder, whereby said suction source assists said powder in flowing into said die cavity; (c) a filter disposed between said suction source and said second port, whereby suction is applied to said die cavity through said filter; and (d) a punch for compressing said powder in said die cavity so as to form said compressed dosage forms; and (e) a purge system for removing powder from said filter; and (f) a powder recovery system for removing excess powder from the vicinity of said die cavity that also includes a recycling means for recovering powder removed from said filter by the purge system and recycling said recovered powder back into said die cavity, either directly or indirectly.

Both independent claims include the feature of an apparatus having a purge zone wherein excess powder is removed from the vicinity of the die cavity and retained powder is purged from the filters and returned for reuse in the die cavity. This combined operating feature is described in the specification in the pages captioned "Compression Module". Specifically, in the purge zone of the apparatus, retained powder is removed from the filters after the compressed dosage

form has been ejected from the die cavities. Positive pressure can be applied using an air pump or pressurized air bank and a pressure manifold. The pressure manifold can have at least one port that is placed in fluid communication with the filters as the die table rotates. Positive pressure cleans out the filters to remove any buildup of powder by transmitting pressurized air from the pressure manifold through the channels and through the die cavities. The powder is blown up through the top of the die cavities into a collection manifold. As also described in the Specification, the purge zone can further include a recovery system to recycle the recovered powder. The recovery system can feed the recovered powder either directly or indirectly back into the die cavities prior to their arrival at the subsequent fill zone.

The recovery system can, for example, also include a shoe block, a blower, a cyclone receiver, a delivery manifold, and an agitator. The shoe block contacts a portion of the periphery of the die table between the pressure manifold and the fill zone to remove excess powder. The shoe block is aligned with the openings in the die table to create a pressure seal between the openings and the shoe block. The blower is coupled to the collection manifold and pulls powder from the die cavities. The blower sends purged powder from the collection manifold to the cyclone dust separator. The cyclone dust separator collects the purged powder and sends the powder to the delivery manifold. The delivery manifold is disposed just above the die table so that as the die table rotates, the top of the die table comes into contact with the delivery manifold, creating a pressure seal between the delivery manifold and the die table. The die cavities are open to the delivery manifold so that purged powder can flow into the die cavities by gravity or other means such as an optional vacuum source. The agitator rotates within the delivery manifold to direct the purged powder to the die cavities. The die table continues to rotate to bring the die cavities back containing the returned, purged powder into the fill zone.

SU '370 appears to disclose a compression machine with lines in the vicinity of the compression zone. Applicants do not have a copy of a translation for this reference or obtain an English abstract. Hence, further differences may be identified upon review of the complete reference. Bullock is a blend reclaim system in which the powder is recovered and recycled back into the bulk blend, rather than being returned to the die cavities without any recombination with

bulk blend feed material. Hence, even assuming that SU '370 can be combined in the manner suggested by the Examiner with Bullock, the resulting combination does not disclose or suggest the instantly claimed invention herein. For this reason, Applicants request that the Examiner reconsider and withdraw his obviousness rejection of the pending claims in view of SU '370 and Bullock.

The Examiner rejects claims 14, 20, 41 and 47 under 35 U.S.C. 103 as being unpatentable over SU '370 taken together with Bullock, as applied above, and further in view of U.S. Patent No. 3,430,532 ("Campbell"). Claims 14, 20, 41 and 47 depend from independent claims 13 and 40. The subject matter of claim 16 has been incorporated into these independent claims, thereby rendering this rejection moot because claims 13 and 40 are, as shown above, allowable over the combination of SU '370 and Bullock. Applicants request that the Examiner reconsider and withdraw his obviousness rejection of claims 14, 20, 41 and 47 in view of SU '370 and Bullock and Campbell.

Applicants submit that the instant application is now in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the Examiner contact the undersigned representative.

Respectfully submitted,

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